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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,484	07/13/2001	Moncef Jendoubi	252/159	3711

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 06/13/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/905,484

Applicant(s)

JENDOUBI, MONCEF

Examiner

Gary W. Counts

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121:

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### **Status of the claims**

The Request for Continued Examination and the amendment filed April 7, 2003 is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how the binding of the antibody to the antigen is related to the polynucleotide sequence encoding the antigen. See also deficiency in claim 15.

Claim 5 is vague and indefinite because it is unclear if the murine polyclonal IgG is derived or expressed by a murine or if Applicant is referring to some other characteristic related to a murine system.

Claim 7 is vague and indefinite because it is unclear what applicant intends. Are 10 different antibodies placed between 100 different antibodies and 10,000 different antibodies or does the array comprise 100 different antibodies up to 10,000 different antibodies.

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***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8 and 15-18 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al (US 6,329,209).

Wagner et al disclose arrays of antibodies which are arranged in discrete, known regions on the portions of a substrate (solid support) surface and wherein each patch comprises antibodies attached thereon. Wagner et al disclose that the antibodies of a given patch are capable of binding a particular antigen and that the array comprises a plurality of different antibodies, each of which is capable of binding a particular antigen (col 2, line 63 – col 3, line 9). Wagner et al disclose that these antibodies may be polyclonal or monoclonal antibodies, or antibody fragments and that the antibodies can be IgG (col 13, lines 6-20). Wagner et al also disclose that the arrays comprise at least about 10 different antibodies and more preferably, at least about 100 different antibodies and may contain 10,000 different antibodies (col 11, lines 1-42). Wagner et al disclose that these antibodies can be derived from natural sources, or partly or wholly synthetically produced. Wagner et al disclose that the antibodies are derived from a mouse (col 26). Wagner et al disclose that the antibody can be isotypes (col. 5, line

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56). Wagner et al disclose that the array can be used as a diagnostic tool in evaluating the status of a tumor or diseased tissue (columns 11, 37 and 38). Wagner et al also disclose using the array with a biochip to form a device (col 37, line 54-59).

With respect to the limitations directed to correlation to expression of the polynucleotide sequence encoding the antigen and correlated on a one-to-one basis with an isolated polynucleotide sequence expressed to encode the protein to which the antibody specifically binds, the fact the binding of the antibody to the antigen is correlated to expression of a polynucleotide sequence encoding the antigen and correlated on a one-to-one basis with an isolated polynucleotide sequence expressed to encode the protein to which the antibody specifically binds is not given patentable weight because the claims are directed to a composition and a device and not a method. Therefore it is unclear how the expressions of the polynucleotide sequence encoding the antigen is related to the array.

3. Claims 1, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Chin et al (US 6,197,599).

Chin et al disclose a device comprising a solid support and multiple immobilized antibodies for protein detection. Chin et al disclose that the antibodies are individually deposited in a predetermined order, so that each of the agents can be identified by the specific position it occupies on the support. Chin et al disclose that the antibodies can be raised by immunizing animals such as a mouse.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al (US 6,329,209).

See above for teachings of Wagner et al.

Wagner et al differ from the instant invention in failing to teach at least 10% of the reaction sites of the array are comprised of aliquots of homogenous antibodies.

With respect to at least 10% of the reactions sites of the array is comprised of aliquots of homogenous antibodies as recited in the instant claims, the optimum percentage of reaction sites to determine an analyte of interest can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

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**Conclusion**

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Bandaru (US 6,462,187) disclose antibody arrays for nucleic acids or polypeptides (col 49).

No claims are allowed.

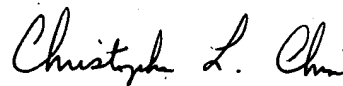
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
June 5, 2003



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 /64/